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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/155,514	11/17/1998	MIE KAINOH	1102-98	8751

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SCHWADRON, RONALD B

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1644

DATE MAILED: 03/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b>	Application No. <b>09/155,514</b>	Applicant(s) <b>Kainoh et al.</b>
	Examiner <b>Ron Schwadron</b>	Art Unit <b>1644</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Feb 1, 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**THE PERIOD FOR REPLY [check only a) or b)]**

- a)  The period for reply expires 6 months from the mailing date of the final rejection.
- b)  In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.  A Notice of Appeal was filed on \_\_\_\_\_ . Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2.  The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3.  The proposed amendment(s) will not be entered because:
  - (a)  they raise new issues that would require further consideration and/or search. (See NOTE below);
  - (b)  they raise the issue of new matter. (See NOTE below);
  - (c)  they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d)  they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

4.  Applicant's reply has overcome the following rejection(s):
   
\_\_\_\_\_  
\_\_\_\_\_
5.  Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).
6.  The a)  affidavit, b)  exhibit, or c)  request for reconsideration has been considered but does NOT place the application in condition for allowance because:
   
see enclosed note
  
\_\_\_\_\_
7.  The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
8.  For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):
   
Claim(s) allowed: none
  
Claim(s) objected to: none
  
Claim(s) rejected: 2-9, 24, 25, and 45-49
  
\_\_\_\_\_
9.  The proposed drawing correction filed on \_\_\_\_\_ a)  has b)  has not been approved by the Examiner.
10.  Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
11.  Other: see enclosed note

**RONALD B. SCHWADRON**  
**PRIMARY EXAMINER**  
**GROUP 1800 (62)**

1. Claims 24,25,45-49 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gallatin et al. and prior art disclosed in the specification (see references disclosed in pages 2 and 3 of specification) for the reasons elaborated in the previous Office Action. Applicants arguments have been considered and deemed not persuasive.

Gallatin et al. teach an  $\alpha$  integrin chain extracellular domain/Ig constant domain fusion protein (see claim 19). The specification, page 11 discloses that "chimeric protein consisting of the  $\alpha$  chain of an integrin and the heavy or light chain of an immunoglobulin" actually means "the extracellular region of the  $\alpha$  chain of an integrin is bound to the constant region of the heavy chain or light chain contained an immunoglobulin". A similar definition is given for "chimeric protein consisting of the  $\beta$  chain of an integrin and the heavy or light chain of an immunoglobulin". The art recognizes that Ig constant domains are found in light or heavy chain of an Ig molecule. Regarding claims 24 and 25, the recitation of an intended use carries no weight in the instant product claims. However, Gallatin et al. does teach pharmaceutical compositions of soluble  $\alpha$  integrin (page 12). Gallatin et al. also teach integrin/Ig fusion proteins derived from a variety of known integrin molecules (see page 37, first paragraph). Gallatin et al. do not teach that the integrin/Ig fusion proteins contain the particular alpha or beta integrin chains recited in the claims. The prior art disclosed in the specification, pages 2 and 3 indicates that all of the integrin chains recited in the claims were known in the art. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Gallatin et al. teach an  $\alpha$  integrin chain extracellular domain/Ig constant domain fusion proteins, while the prior art disclosed in the specification, pages 2 and 3 indicates that all of the integrin chains recited in the claims were known in the art. One of ordinary skill in the art would have been motivated to do the aforementioned because Gallatin et al. teach integrin/Ig fusion proteins derived from a variety of known integrin molecules (see page 37, first paragraph) and that said molecules can be used in immunoassays (see page 37, first paragraph). Gallatin et al. also teach pharmaceutical compositions containing integrin/Ig fusion proteins (see page 12, first paragraph). The amino acid sequences of the Ig heavy chain and integrins recited in the claims were known in the art.

Regarding applicants comments, Gallatin et al. teach the fusion protein can contain an intact alpha chain (see page 7, first incomplete paragraph).

2. Claims 2-9,24,25,45-49 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Carter et al. (US Patent 5,821,333) in view of Hori et al. (US Patent 5,916,771) and prior art disclosed in the specification (see references disclosed in pages 2 and 3 of specification) for the reasons elaborated in the previous Office Action. Applicants arguments have been considered and deemed not persuasive.

Carter et al. teach recombinant fusion proteins containing an adhesion molecule linked to a constant heavy chain derived from an Ig molecule (see columns 19 and 20). Carter et al. teach that such molecules can be dimers, wherein the two chains contain different adhesion molecules wherein the two adhesion molecules are both fused to heavy chain Ig constant regions (see column 19, last paragraph, continued on next page). Carter et al. do not specifically teach that the adhesion molecules are derived from an  $\alpha$  and  $\beta$  chain of an integrin. Hori et al. teach that  $\beta_1$  integrin molecules were known in the art as heterodimeric molecules (see column 5). The prior art disclosed in the specification, pages 2 and 3 indicates that all of the integrin chains recited in the claims were known in the art. The prior disclosed in the specification, page 3 indicates that  $\beta_1$  integrin molecule was known in the art as heterodimeric molecule containing a  $\beta_1$  and an  $\alpha 4$  chain. Carter et al. teach that Ig fusion proteins have a variety of art recognized uses (see column 4). Hori et al. teach recombinantly produced dimeric integrin molecules (see column 5). Carter et al. also teach recombinantly produced dimeric adhesion molecules (see columns 19 and 20). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Carter et al. teach recombinant fusion proteins containing an adhesion molecule linked to a constant heavy chain derived from an Ig molecule while Hori et al. teach that  $\beta_1$  integrin molecules were known in the art as heterodimeric molecules and that such molecules can be recombinantly produced. One of ordinary skill in the art would have been motivated to do the aforementioned because Carter et al. teach that Ig fusion proteins have a variety of art recognized uses (see column 4). Carter et al. teach use of Ig fusion proteins as drugs (see column 4). The various integrin molecules recited in the claims were all known in the art. Human Ig heavy chain sequences are known in the art (see Carter et al., columns 18 and 19).

Regarding applicants comments, Carter et al. teach recombinant fusion proteins containing an adhesion molecule linked to a constant heavy chain derived from an Ig molecule (see columns 19 and 20). Carter et al. teach that such molecules can be dimers, wherein the two chains contain different adhesion molecules wherein the two adhesion molecules are both fused to heavy chain

Ig constant regions (see column 19, last paragraph, continued on next page). Carter et al. teach that immunoadhesions have a variety of art recognized uses (see column 4, third paragraph). Integrins are art known adhesion molecules. All of the integrin chains recited in the claims were known in the art. Carter et al. teach that immunoadhesins have a variety of art recognized uses for therapeutic and diagnostic purposes (see column 4, third paragraph). One of ordinary skill in the art would have been motivated to do have created the claimed invention in view of the cited references because Carter et al. teach that adhesion molecule/Ig fusion proteins have a variety of art recognized uses and integrins are adhesion molecules.

Regarding applicants comments about Hori et al., Hori et al. does not address the method/products of Carter et al. because Hori et al. does not disclose or deal with chimeric immunoadhesion molecules. Furthermore, Hori et al. does not address or even disclose the Carter et al. patent. Regarding claims 3 and 4 of Hori et al., said claims are drawn to a method of making an antibody (eg. not the claimed invention) and are irrelevant to the issue under consideration. The teachings of Hori et al. are relied upon in the instant rejection as disclosing that  $\beta_1$  integrin molecules were known in the art as heterodimeric molecules and that such molecules can be recombinantly produced. Hori et al. does not disclose or deal with chimeric immunoadhesion molecules.

6. No claim is allowed.

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Serial No. 09/155514

Art Unit 1644

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Ronald B. Schwadron  
Primary Examiner  
Group 18001 *b2*

Ron Schwadron, Ph.D.

Primary Examiner

Art Unit 1644